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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,823	08/22/2001	Corrado Fogher	4161-14	8610

23117 7590 07/26/2006

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,823	FOGHER, CORRADO	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59,61,63,68,69,71,73,78-85 and 91-123* is/are pending in the application.

4a) Of the above claim(s) *92-97 and 112-117* is/are withdrawn from consideration.

5)☒ Claim(s) *98-111* is/are allowed.

6)☒ Claim(s) *59,61,63,68,69,71,73,78-85,91 and 118-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed March 27, 2006 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on February 13 and March 27, 2006 have been entered.

Claims 1-58, 60, 62, 64-67, 70, 72, 74-77 and 86-90 are cancelled.

Claims 59, 61, 63, 68, 71, 73, 78 and 91 are currently amended in the amendment filed February 13, 2006.

Claims 63, 73 and 98 are currently amended in the amendment filed March 27, 2006.

Claims 96-97 are withdrawn-currently amended in the amendment filed February 13, 2006.

Claims 98-117 are new in the amendment filed February 13, 2006.

Claims 118-123 are new in the amendment filed March 27, 2006.

Claims 59, 61, 63, 68-69, 71, 73, 78-85 and 91-123 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 112-117 are directed to an invention that is independent or distinct from the invention originally elected for the following reasons: the originally elected invention of Group V was directed to a plant expression cassette including the 7s basic globulin promoter and plants comprising said expression cassette, and to a method of using said expression cassette for plant transformation. Newly submitted claims 112-117 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A product and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

A) The technical feature linking the invention of originally elected Group V and newly submitted claims 112-117 is a plant expression cassette that expresses in seed with

tissue-specific expression a non-degraded human lactoferrin, said cassette comprising a gene encoding human lactoferrin, said gene being operatively linked to DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, However, such an expression cassette is obvious over Salmon V. et al. (Production of Human Lactoferrin in Transgenic Tobacco Plants, Protein Expression and Purification, Volume 13, Issue 1, Pages 127-135, June 1998, Applicant's IDS) in view of Parmenter D.L. et al. (Production of biologically active hirudin in plant seeds using oleosin partitioning. Plant Mol Biol. 1995 Dec;29(6):1167-80) and van der Geest A. et al. (A 68 bp element of the beta-phaseolin promoter functions as a seed-specific enhancer. Plant Mol Biol. 1996 Nov;32(4):579-88), and therefore does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. The special technical feature of each of newly submitted claims 112-117 is the particular method or product characteristic of each claim.

and B) The allowed combinations do not include multiple products (nutriceutical) or multiple methods of using products (lactoferrin production methods, flour production method, functional food production method), as claimed in claims 92-97; See MPEP § 1850.

Applicant's claims do not have a special technical feature which links the inventions one to the other, and they encompass additional product and multiple methods of using products, and they thus lack unity of invention.

Since applicant has received an action on the merits for the originally presented invention, claims 112-117 are withdrawn from consideration as being directed to non-elected inventions.

Claim Rejections - 35 USC § 112

Claims 59, 61, 63, 68, 69, 71, 73, 78-85 and 91 remain rejected, and claims 118-123 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

Applicant's arguments filed February 13, 2006 have been fully considered but they are not persuasive.

Applicant traverses on the grounds that the specification teaches a representative number of species within the claimed genus. Applicant points out that regulatory elements (e.g., promoter and leader sequence) for a gene encoding soybean protein 7S basic globulin are taught. Applicant also points out that another gene encoding soybean protein 7S basic globulin was disclosed by Watanabe Y. et al. (Nucleotide sequence of the basic 7S globulin gene from soybean. Plant Physiol. 1994 Jul;105(3):1019-20). Applicant additionally points out that Kagawa H. et al. (Sequence of a cDNA encoding soybean basic 7S globulin. Nucleic Acids Res. 1989 Nov 11;17(21):8868) disclosed a CDNA for soybean protein 7S basic globulin. Applicant further points out that Shu T.F. et al. (GenBank Accession U59425, Glycine max 7S seed globulin precursor, mRNA, complete cds. July 3, 1996) disclose another CDNA for soybean protein 7S basic globulin. Applicant further points out that Watanabe et al. indicated that Southern hybridization suggested that at least four copies of genes encoding 7S basic globulin exist in the soybean genome. Applicant maintains that taken together, the Applicant's teachings

and the knowledge in the art provide more than adequate support for a generic description of the regulatory sequences (e.g., promoters, terminators, enhancers, leader sequences) of the expression cassette. Applicant also points out that SEQ ID NO: 21 differs from the corresponding sequence disclosed by Watanabe et al. by about 5%. Applicant also teaches on page 11 of the specification that sequences in the promoter region involved in gene regulation (e.g., CAAT and TATA box sequences, heat shock elements that act as enhancers) have been identified. One of skill in the art would recognize from the consensus sequences described in the transcriptional regulatory region of the gene for soybean protein 7S basic globulin and the polymorphisms that were known at the time this application was filed that the claimed genus of regulatory sequences is adequately described in Applicant's specification. In contrast, examples in this specification of transcriptional regulatory regions from other soybean genes (e.g., SEQ ID NO: 22 from the beta conglycinine genes) teach what does not belong to the claimed genus. (reply pages 8-9)

The rejection is maintained because the genus of requisite regulatory sequences (i.e. soybean protein 7S basic globulin promoter and leader sequences) is not adequately described. The gene sequence encoding soybean protein 7S basic globulin disclosed by Watanabe Y. et al. does not support a description of the genus of requisite regulatory sequences because Watanabe Y. et al. did not isolate and functionally charcaterize the requisite regulatory sequences (soybean protein 7S basic globulin promoter and leader sequences). Further, the disclosure by Watanabe et al. that Southern hybridization suggests that at least four copies of genes encoding 7S basic globulin exist in the soybean genome does not describe the structural attributes of the regulatory sequences that might

be obtained from such genes. The soybean protein 7S basic globulin cDNA sequences disclosed by Kagawa H. et al. and Shu T.F. et al. do not support a description of the genus of requisite regulatory sequences because Kagawa H. et al. and Shu T.F. et al. did not isolate and functionally charcaterize the requisite regulatory sequences (soybean protein 7S basic globulin promoter and leader sequences). Sequences in the promoter region involved in gene regulation (e.g., CAAT and TATA box sequences, heat shock elements that act as enhancers) identified by Applicant on page 11 of the specification do not support a description of the genus of requisite regulatory sequences because these sequences are not unique to the requisite regulatory sequences (soybean protein 7S basic globulin promoter and leader sequences).

Claim Rejections - 35 USC § 103

Claims 59, 69, 79-85 and 91 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Salmon V. et al. (Production of Human Lactoferrin in Transgenic Tobacco Plants, Protein Expression and Purification, Volume 13, Issue 1, Pages 127-135, June 1998, Applicant's IDS) in view of Parmenter D.L. et al. (Production of biologically active hirudin in plant seeds using oleosin partitioning. Plant Mol Biol. 1995 Dec;29(6):1167-80) and van der Geest A. et al. (A 68 bp element of the beta-phaseolin promoter functions as a seed-specific enhancer. Plant Mol Biol. 1996 Nov;32(4):579-88), for reasons of record.

Applicant's arguments filed February 13, 2006 have been fully considered but they are not persuasive.

Applicant maintains that Salmon et al. do not disclose a plant expression cassette or a recombinant DNA vector that expresses human lactoferrin in seed, or DNA sequences comprising the promoter and the leader sequence of soybean protein 7S basic globulin. Applicant also maintains that the failure of Salmon et al. to teach or suggest the claimed invention is not remedied by the attempt to modify that disclosure with Parmenter et al. and van der Geest et al., as Parmenter et al. disclose the oleosin promoter and leader sequences from *Arabidopsis*, whereas van der Geest et al. disclose the beta phaseolin promoter and leader sequences from *Phaseolus*. Applicant maintains that the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made as the cited references fail to teach or suggest using the promoter and leader sequences from the soybean gene encoding protein 7S basic globulin. (reply page 11)

The Examiner maintains that Salmon et al. was not cited for teaching a plant expression cassette or a recombinant DNA vector that expresses human lactoferrin in seed, or DNA sequences comprising the promoter and the leader sequence of soybean protein 7S basic globulin. The outstanding rejection expressly states (at page 10 of the office action mailed October 11, 2005) that "Salmon V. et al. do not teach a recombinant DNA vector and plant expression cassette that expresses in seed with tissue-specific expression, or DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin.". Salmon V. et al. was cited for teaching recombinant DNA vectors and plant expression cassettes comprising a gene encoding human lactoferrin, said gene being operatively linked to an enhanced 35S promoter of CaMV and either a polynucleotide encoding a signal peptide of human lactoferrin, or a

polynucleotide encoding a signal peptide of sporamin (page 130 Figure 1), the production of transgenic tobacco plants by transforming tobacco cells with said cassettes and vectors by *Agrobacterium*-mediated transformation of tobacco leaf discs, which process inherently involves cellular aggregations including calluses capable of regenerating transgenic plants (page 128 column 2 second full paragraph; page 130 column 1 *Generation of hLF-Expressing Transgenic Tobacco Plants*), and the expression of non-degraded human lactoferrin (page 132 paragraph spanning columns 1 and 2).

The Examiner also maintains that the DNA sequences coding for the promoter and the leader sequences of the [beta]-phaseolin (phas) gene taught by van der Geest A. et al. are the same as DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, since a name such as "of soybean protein 7S basic globulin" imparts no particular structural characteristics to a promoter or leader polynucleotide, such that any promoter and leader polynucleotides that express in seed with tissue-specific expression an operatively linked gene are the same as promoter and leader polynucleotides "of soybean protein 7S basic globulin".

Given the success of Salmon V. et al. in expressing a non-degraded human lactoferrin in plant cells using plant expression vectors, given the success of Parmenter D.L. in expressing an oleosin-hirudin fusion protein in seed with tissue-specific expression using a plant expression vector, and the teaching of Parmenter D.L. that seeds possess a number of characteristics that make them highly suitable for the production of recombinant proteins in plants, and given the success of van der Geest A. et al. in expressing a reporter gene in seed with tissue-specific expression using a plant expression vector comprising a reporter gene operatively linked to DNA sequences coding for the

promoter and the leader sequences of the [beta]-phaseolin (phas) gene, which are the same as DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to express in seed with tissue-specific expression a non-degraded human lactoferrin using a plant expression cassette that comprises a gene encoding human lactoferrin operatively linked to DNA sequences coding for the promoter and the leader sequences of soybean protein 7S basic globulin. One skilled in the art would have been motivated to do so in order to produce recombinant lactoferrin in plant seed. One skilled in the art would have had a reasonable expectation of success given the success of Salmon V. et al. in expressing a non-degraded human lactoferrin in plant cells, given the success of Parmenter D.L. in expressing an oleosin-hirudin fusion protein in seed with tissue-specific expression, and given the success of van der Geest A. et al. in expressing a reporter gene in seed with tissue-specific expression. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims 98-111 are allowed.

Remarks

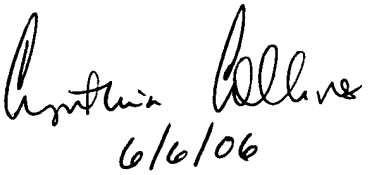
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC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